

CLAIMS

What is claimed is:

1. A method for eliciting an immune response in a vertebrate  
5 subject, said method comprising administering constructs carrying genomic  
DNA fragments from one or more pathogens to the subject in an amount  
sufficient to elicit an immune response against antigen encoded by a sequence  
contained in said genomic DNA fragments, wherein the genomic DNA  
fragments are greater than 5 kilobases in size.  
10
2. The method of claim 1, wherein expression of coding  
sequences contained within the genomic DNA fragments is not driven by a  
heterologous promoter.
- 15 3. The method of claim 1, wherein the construct is a plasmid.
4. The method of claim 3, wherein the genomic fragments are  
between about 5 kilobases and 25 kilobases in size.
- 20 5. The method of claim 3, wherein at least one of the pathogens is  
a virus.
6. The method of claim 5, wherein the virus is herpes simplex  
virus-2 (HSV-2).  
25
7. The method of claim 5, wherein the genomic fragments are  
from more than one virus.
8. The method of claim 1, wherein the administering is by  
30 transdermal administration.

9. The method of claim 1, wherein the construct is a cosmid.

10. The method of claim 9, wherein the genomic fragments are between about 25 kilobases and 50 kilobases in size.

5

11. The method of claim 9, wherein at least one of the pathogens is a virus.

12. The method of claim 11, wherein the virus is herpes simplex virus-2 (HSV-2).

10

13. The method of claim 9, wherein the genomic fragments are from more than one virus.

14. The method of claim 9, wherein the administering is by transdermal administration.

15

~~15. A method for eliciting an immune response in a vertebrate subject, said method comprising:~~

~~(a) providing a core carrier coated with constructs carrying genomic DNA fragments derived or obtained from one or more pathogens, wherein the genomic DNA fragments contain an antigen coding sequence, and are greater than 5 kilobases in size; and~~

~~(b) administering the coated core carrier to the subject using a particle-mediated transdermal delivery technique, whereby antigen encoded by a coding sequence present in the genomic DNA fragments is expressed in the subject in an amount sufficient to elicit an immune response.~~

20

25

16. The method of claim 15, wherein expression of coding sequences contained within the genomic DNA fragments is not driven by a heterologous promoter.

Sub 5 92 17. ~~The method of claim 15, wherein the construct is a plasmid.~~

18. The method of claim 17, wherein the genomic fragments are between about 5 kilobases and about 25 kilobases in size.

10 19. The method of claim 17, wherein at least one of the pathogens is a virus.

20. The method of claim 19, wherein the virus is herpes simplex virus-2 (HSV-2).

15 21. The method of claim 19, wherein the genomic fragments are obtained or derived from more than one virus.

20 22. The method of claim 15, wherein the core carrier has an average diameter of about 0.5 to about 5  $\mu\text{m}$  and a density sufficient to allow delivery into the subject.

23. The method of claim 22, wherein the core carrier is comprised of a metal.

25 24. The method of claim 23, wherein the metal is gold.

25. The method of claim 15, wherein step (b) is repeated to provide a prime and a booster administration.

1000 900 800 700 600 500 400 300 200 100 0

Sub. 93

26. The method of claim 15, wherein the construct is a ~~cosmid~~.
27. The method of claim 26, wherein the genomic fragments are between about 25 kilobases and about 50 kilobases in size.
- 5 28. The method of claim 26, wherein at least one of the pathogens is a virus.
- 10 29. The method of claim 28, wherein the virus is herpes simplex virus-2 (HSV-2).
30. The method of claim 28, wherein the genomic fragments are obtained or derived from more than one virus.
- 15 31. The method of claim 26, wherein the core carrier has an average diameter of about 0.5 to about 5  $\mu\text{m}$  and a density sufficient to allow delivery into the subject.
- 20 32. The method of claim 31, wherein the core carrier is comprised of a metal.
33. The method of claim 32, wherein the metal is gold.
34. The method of claim 26, wherein step (b) is repeated to provide a prime and a booster administration.
- 25 35. A method for identifying a sequence encoding an antigenic polypeptide, the method comprising:
- (a) administering one or more constructs carrying genomic DNA fragments from one or more pathogens to a subject, wherein the genomic
- 30

DNA fragments are greater than about 5 kilobases in size and contain a coding sequence for said antigenic polypeptide and further wherein, upon delivery, the antigenic polypeptide is expressed from said coding sequence in an amount sufficient to elicit an immune response; and

- 5           (b)     identifying the coding sequence on the construct which encodes the antigenic polypeptide.

36.     The method of claim 35, wherein step (b) comprises administering one or more fragments of the constructs of step (a) and  
10     identifying which fragment encodes the antigenic polypeptide.

37.     The method of claim 35, wherein step (b) comprises sequencing the construct.

15           38.     A vaccine composition comprising one or more constructs containing genomic DNA fragments obtained or derived from one or more pathogens, wherein the genomic fragments are greater than 5 kilobases in size and contain at least one antigen coding sequence.

20           39.     The vaccine composition of claim 38, wherein the construct is a plasmid.

40.     The vaccine composition of claim 39, wherein the genomic fragments are between about 5 kilobases and about 25 kilobases in size.

25

41.     The vaccine composition of claim 38, wherein expression of coding sequences contained in the genomic DNA fragments is not driven by a heterologous promoter.

42. The vaccine composition of claim 38, wherein at least one of the pathogens is a virus.

43. The vaccine composition of claim 42, wherein the virus is herpes simplex virus-2 (HSV-2).

44. The vaccine composition of claim 42, wherein the genomic fragments are from more than one virus.

45. A vaccine composition comprising nucleic acid constructs carrying genomic DNA fragments from herpes simplex virus-2 (HSV-2).

46. The vaccine composition of claim 45, wherein expression of coding sequences contained within the genomic DNA fragments is not driven by a heterologous promoter.

47. The vaccine composition of claim 45, wherein the construct is a plasmid.

48. The vaccine composition of claim 47, wherein the genomic fragments are between about 5 kilobases and 25 kilobases in size.

49. The vaccine composition of claim 45, wherein the construct is a cosmid.

50. The vaccine composition of claim 49, wherein the genomic fragments are between about 25 kilobases and 50 kilobases in size.

51. The vaccine composition of claim 45, wherein at least one the said genomic DNA fragments from HSV-2 corresponds to the sequence extending from the 7th to 10th EcoR1 sites shown in Figure 1.